REMARKS

Upon entry of the amendments above, claims 35-54 are pending. Claim 35 is amended and new claims 49-54 are presented.

Telephone Interview

Applicants gratefully acknowledge the telephone interview with Examiner Thomas Sweet on May 14, 2007. During the interview, the Applicants discussed the Office Action and the Yang reference cited therein (WO-00/45744).

Claim Amendments

The Applicants have amended the claims to focus on a preferred embodiment described in the specification, for example in Figure 8. All new claims are supported in the specification as originally filed. No new matter is added.

Support for the recitation of the method of delivering lipophilic bioactive material recited in claim 35 is found, for example, at paragraphs [0006], [0014], [0015], [0017], [0032] of the corresponding published application (US 2004-0073284 A1). Support for the recitation of inflation times of up to about one minute is found at paragraph [0014]; recitation of paclitaxel or paclitaxel derivative bioactive material is found at paragraph [0058]; recitation of a bioactive material comprising a diagnostic agent is found at paragraph [0011]; recitation of a blood vessel or coronary artery as a body vessel is found at paragraphs [0012] and [0045]; recitation of "a total of about 5 to about 500 μg of the lipophilic bioactive material" is found at paragraph [0068]; recitation of "without implanting a stent within the body vessel" is supported at paragraph [0093]; recitation of a balloon comprising a polyamide, polypropylene, PEBAX and polyethylene is found at paragraphs [0020] and [0021]; recitation of transferring the bioactive material to the inner wall of the body vessel is found at paragraph [0014]; recitation of percutaneous insertion of the expandable balloon is found at paragraph [0006]; support for recitation of contacting the inflated

balloon with the inner wall of the body vessel for up to about 20 minutes is found in paragraph [0100]; and support for the recitation of 0.2 to about 20 μg of paclitaxel or a paclitaxel derivative per mm^2 is found in paragraph [0068] (i.e., 5-500 μg/25mm^2).

Claim Rejections

Claim Rejections under 35 USC §102

Claims 35, 36-40, 42 and 45 stand rejected under 35 USC §102(b) for allegedly being anticipated by the published patent application WO00/45744 ("Yang"). In particular, the Examiner asserts that Yang teaches a method that includes delivering a bioactive material using a balloon "being free of (none disclosed): a coating atop the bioactive material, a time-release layer, a containment material and a containment layer (abs)" (Office Action at page 3).

Applicant respectfully traverses this rejection. Yang does not teach or suggest inserting a portion of medical device including a balloon into a body vessel, where the balloon being free of: a coating atop the bioactive material, the balloon being free of a time-release layer, the balloon being free of a containment material and the balloon being free of a containment layer. Instead, Yang describes methods of treatment using a two-layer coating with a "thin layer... of a polymeric material" overlying a releasable drug or therapeutic substance layer" (Yang at page 3, lines 14-17). This "thin layer" - also called a "second or overlying layer" (Yang at page 4, line 12) and the "second coating" (Yang at page 6, line 2) – "fractures upon expansion of the medical device..." and "...prevents elution of the drug or therapeutic substance during the time required to place the device within the vessel lumen" (Yang at page 4, lines 12-16). Yang further teaches that the "second coating... fractures during expansion of the... medical device... to allow elution of the drug or therapeutic substance through the fissures formed through the surface of the second coating" (Yang at page 6, lines 2-7). In fact, "[t]he second coating overlying the drug or therapeutic substance is... relatively inelastic so that upon expansion of the balloon, the coating fractures to allow elution of the drug or therapeutic substance through fissures

formed in the coating" (Yang at page 7, lines 3-6). Applicants request reconsideration and withdrawal of this rejection.

Claim Rejections under 35 USC §103

Claims 36, 43 and 47 stand rejected under 35 USC §103(a) for allegedly being obvious over Yang recited above in view of either US 6,491,619 ("Trauthen"), US 6,203,487 ("Consigny), US 6,214,333 ("Zoldhelyi"), US 6,706,892 ("Ezrin") or US 6,867,190 ("Carney"). by the published patent application WO00/45744 ("Yang"). In particular, the Examiner asserts that the recitation of inflation times "up to about one minute" are taught by Trauthen, Consigny, Zolhelyi, Exrin and/or Carney, that selection of certain claimed balloon materials "would have been obvious," and that "each of the references... demonstrates repeated inflations of less than about 20 minutes demonstrating the inherent or obviousness of the limitation" (Office Action at page 5). In addition, claims 41, 45 and 48 stand rejected under 35 USC 103(a) over Yang in view of US2003/0059454 ("Barry") (Office Action at pages 5-6). The Examiner notes that while "Yang remains silent as to disclosing any dosing levels including about 5-500 micrograms," Barry teaches dosage ranges of 50 – 345 micrograms (Office Action at page 6). Therefore, according to the Office Action, the claimed dose range "is obvious, since this can be determined by experimentation" (Office Aciton at page 6). Claim 46 stands rejected under 35 USC 103(a) as allegedly being obvious over Yang in view of Barry and in further view of either Trauthen, Consigny, Zoldhelyi, Ezrin or US 6,867,190 ("Carney") (Office Action at pages 6-7). The Examiner notes that while "Yang as modifies remains silent as to any inflation time," and "silent as to maintained in contact with the inner wall of the body vessel for up to about 20 minutes," Trauthen, Consigny, Zolhelyi, Ezrin and Carney each teach performing angioplasty "with a minute or less inflation time over repeated intervals" (Office Action at page 6). Therefore, according to the Office Action, the claimed dose range "is obvious, since this can be determined by experimentation" (Office Aciton at page 6).

Applicant respectfully disagrees. Neither Yang, alone or in combination with Trauthen, Consigny, Zoldhelyi, Ezrin and/or Carney, teach or suggest inserting a portion of medical device including a balloon into a body vessel, where the balloon being free of: a coating atop the bioactive material, the balloon being free of a time-release layer, the balloon being free of a containment material and the balloon being free of a containment layer.

Claim Rejections under 35 USC §112

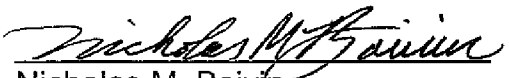
Claim 47 is rejected under 35 USC §112, first paragraph, for allegedly failing to comply with the written description requirement. In particular, the Examiner asserts that "[p]aragraph 100 does not support 'up to' to minutes..." (Office Action at page 3). Applicants have elected to amend claim 47 to focus on other embodiments of the invention wherein "the outer surface of the inflated balloon is maintained in contact with the inner wall of the body vessel for only the period of the inflation of the balloon," for example as described in paragraph [0058] of the published application (US2004/0073284 A1). Reconsideration and withdrawal of this rejection is requested.

Conclusion

If, for any reason, the Examiner is unable to allow the application and feels that an interview would be helpful to resolve any remaining issues, he is respectfully requested to contact the undersigned attorney at (317) 636-0886.

Respectfully submitted,

Dated: July 18, 2007



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